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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,250	10/17/2005	Hiroshi Kase	00005.001217.	6976

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
03/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,250	KASE ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25 and 71-80* is/are pending in the application.

4a) Of the above claim(s) *25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 71-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants present arguments over the 35 USC 103 rejection. In particular, Applicants argue that Goodman & Gilman's provides no basis to allege that any antidepressant is useful for all anxiety disorders. Applicants argue that the presently claimed compound, istradefylline, has unexpected superiority over adenosine A_{2A} receptor antagonists that are closer to those known in the prior art. Applicants point to test examples 1, 4 and 6 and assert that istradefylline shows vastly more potent activity in animal models of anxiety than Compounds C^2 and C. Applicants argue that Compound C is a compound having a triazolopyrimidine skeleton as in the Greenlee reference.

In response to the above arguments, it is noted that Greenlee was used for the general teaching that A_{2A} receptor antagonists are useful in treating anxiety-related disorders. Regarding the argument that istradefylline has superior results over Compound C, which Applicants assert is a compound structurally similar to those used in the Greenlee reference, it is noted that the tests run show results for each compound over vehicle; however, there is nothing to compare the effects of the compounds against each other to show that istradefylline has a superior effect. Therefore, the argument that istradefylline has unexpected results over Compound C is not convincing. Accordingly the rejection is being maintained and is given below for Applicants convenience.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23 and 71-80 rejected under 35 U.S.C. 103(a) as being unpatentable over Greenlee et al. (US PgPub 2003/0139395) in view of Suzuki et al. (US Patent 5,543,415) and Goodman & Gilman's: The Pharmacological Basis for Therapeutics, Tenth Edition, 2001, page 469.

Greenlee et al. teach that compounds with adenosine A_{2a} receptor antagonist activity are useful in treating anxiety-related disorders in combination with antidepressants or anxiolytic agents (paragraph 0008). Examples of anxiety-related orders include generalized anxiety disorder, obsessive-compulsive disorders, panic attack, social phobias and post-traumatic stress disorder (paragraph 0008). Common anxiolytic agents that can be administered with the adenosine A_{2a} receptor antagonist are listed in paragraph 0198 and include agents that do not have action at the adenosine A_{2a} receptor.

Greenlee does not teach (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine as the adenosine A_{2a} receptor antagonist.

Suzuki et al. teach antidepressant compositions containing a xanthine derivative or a pharmaceutically acceptable salt thereof, with the xanthine derivative being represented by Formula I (Col. 2, lines 1-41). In particular, Compound 74 overlaps with

present claims 21 and 23 (see Table 1 and Reference Example 71). Test Example 1 shows the effectiveness of the compounds of Formula I (including Compound 74) in an animal model of depression. The xanthine derivatives are known for their adenosine antagonistic action (Col.1, lines 29-49).

Goodman & Gilman's teaches that antidepressants are leading choices in the treatment of severe anxiety disorders, including generalized anxiety disorder, social phobia and obsessive-compulsive disorder and including the common comorbidity of anxiety in depressive illness (page 469).

Accordingly, one would be motivated to combine the teachings of Greenlee et al. which teach the treatment of anxiety disorders, such as generalized anxiety disorder, with adenosine A_{2a} receptor antagonists with Suzuki et al., which teach that compounds such as (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) are antidepressants and the teachings of Goodman & Gilman's which teach that antidepressants are the leading choice in the treatment of severe anxiety disorders. Because Greenlee teaches that adenosine A_{2a} receptor antagonists are an effective treatment option for anxiety and Suzuki teaches that (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) is a A_{2a} receptor antagonist that is an antidepressant and Goodman & Gilman's teaches that antidepressants are the leading choice for treating severe anxiety, one would be motivated to use the (E)-3-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine) which is known as an anti-depressant, to treat anxiety.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627